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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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| 09/232,880 | 01/15/99 | XU J | 210121.428C6 |

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| EXAMINER | |
|---|---|
| HARRIS, A | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1642 | 14 |

**DATE MAILED:** 02/13/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

| Application No. | Applicant(s) |
|---|---|
| 09/232,880 | Xu et al. |
| **Examiner** | **Group Art Unit** |
| Alana M. Harris, Ph. D. | 1642 |

☒ Responsive to communication(s) filed on *November 27, 2000.*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**

☒ Claim(s) *1-6, 8, 9, and 11-39* is/are pending in the applicat

Of the above, claim(s) *1-6 and 13-25* is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *8, 9, 11, 12, and 26-39* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

**Application Papers**

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

*--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---*

## DETAILED ACTION

### *Response to Amendment*

1. Claims 1-6, 8, 9 and 11-39 are pending.

Claims 7 and 10 have been canceled.

Claims 26-39 have been added.

Claims 1-6 and 13-25, drawn to non-elected inventions are withdrawn from examination.

Claims 8, 9, 11, 12 and 26-39 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Priority*

3. Acknowledgment is made of applicant's claim for priority under 35 U.S.C. § 120. The Examiner has reviewed all of the continuation-in part applications. The limitations of SEQ ID Nos: 308, 311, 313 and 326 are not disclosed in the aforementioned applications, hence they receive the instant application's effective filing date of January 15, 1999. As the Applicants noted sequence numbers 45 and 67 were first disclosed in U.S. Application Serial No. 08/904,809, filed August 1, 1997. And SEQ ID NO:107 was first disclosed in U.S. Application Serial No. 09/020,747, filed February 9, 1998. Thus, claims 26, 27, 33 and 34 will be granted the priority date of August 1, 1997. Claims 28 and 35 will be granted the priority date of February 9, 1998.

And claims 29-32 and 36-39 will receive the priority date of January 15, 1999, the effective filing date of the instant Application No. 09/232,880. Dependent claims 8, 9, 11 and 12 will receive the priority date of the instant application because each disclose material filed January 15, 1999 and claims are given the priority date in which all limitations in the claims are found.

***Withdrawn Rejections***

***Claim Rejections - 35 U.S.C. § 112***

4. The rejection of claims 7-12 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicants' cancellation of independent claims 7 and 10.

5. The rejection of claims 7-12 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been withdrawn in view of Applicants' cancellation of claims 7 and 10 and amendments.

*Claim Rejections - 35 U.S.C. § 101*

6. The rejection of claims 7-12 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility, a credible or a well established utility have been withdrawn in view of Applicants' cancellation of claims 7 and 10, as well as Applicants' arguments.

*Claim Rejections - 35 U.S.C. § 102*

7. The rejection of claims 7-12 under 35 U.S.C. 102(a) as being anticipated by WO 98/37418 (August 27, 1998) and WO 98/37093 (August 27, 1998) are withdrawn in view of cancellation of claims 7 and 10.

*New Grounds of Rejection*

*Claim Rejections - 35 U.S.C. § 112*

8. Claims ~~8-12~~ and 26-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The reasons for this rejection are of record in paper number 9, mailed July 20, 2000, see ~~claim~~ number 5.

Applicants' arguments were directed to claims 7-12, which were rejected in the first action of the merits mailed July 20, 2000. These claims have since been either canceled or amended, thus obviating the rejection. Notwithstanding, the claims 8-12 and 26-39 now examined are encompassed within the same scope as claims rejected in the action of July 20, 2000. Applicants' arguments express that with the amendments to the claims and "... that one of skill in the art...provided with the instant specification, would indeed believe that the applicants were in possession of the presently claimed invention at the time the application was filed...". This is found unpersuasive.

Applicant has not provided any specific arguments to the rejection and it is not clear how the amendment overcomes the rejection.

MS 112nd

9. Claims 8, 9, 11, 12 and 26-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Canceled 26, 31-33, 38 & 39.

a. The recitations "oligonucleotide that hybridizes to SEQ ID NO:x" and "...polynucleotide that hybridizes to the oligonucleotide..." and "under moderately stringent conditions" in claims 26-39 are not clear. The metes and bounds are unclear and in the absence of limitations specifying specific stringency conditions.

*Claim Rejections - 35 U.S.C. § 102*

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

drop Cancelled

11. Claims 8, 9, 11, 12, ~~26, 32, 38~~ and ~~39~~ are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent Number 5,786,148 (filed November 5, 1996). U.S. Patent #5,786,148 (see column 1, lines 5-10; column 22, lines 1-31; column 23, lines 10-31; columns 28, lines 64-column 30, line 48; Sequence number 2 of columns 33-36 and accompanying nucleic acid database sheet) disclose methods for determining the presence or absence of prostate cancer in a patient and for monitoring the progression of a cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient with an oligonucleotide that hybridizes to SEQ ID NO: 2, which contains homologous sequences from the instant applications SEQ ID NOs:45 and 326 under moderately stringent conditions,

(b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions, wherein the biological sample is selected from the group consisting of body fluids or cell extracts, and

(c) repeating steps (a) and (b) using a biological sample obtained from the patient at a subsequent point in time;

(d) comparing the amount of polynucleotide detected in step (c) to the amount detected in step (b) and therefrom monitoring the progression of the cancer in the patient.

In addition, the method of the reference determines the amount of polynucleotide that hybridizes to the oligonucleotide using polymerase chain reaction and a hybridization assay. The method of the instant application also does this.

***Claim Rejections - 35 U.S.C. § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

drop Cancelled
13. Claims 8, 9, 11, 12, ~~31~~ and ~~38~~ are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 98/45420 (October 15, 1998). Document WO 98/45420 (see page 25, III-page 31, line 7; page 46, lines 15- page 47, line 29; page 69, lines 8-11 and Accession number V62429 of the accompanying nucleic acid database sheet) teaches a method for determining the presence or absence of prostate cancer in a patient and for monitoring the progression of a cancer in a patient, comprising the steps of:

(a) contacting a biological sample obtained from a patient with an oligonucleotide that hybridizes to SEQ ID NO: 3, which contains homologous sequences from the instant applications SEQ ID NO: 3.13 under moderately stringent conditions and

(b) detecting in the sample an amount of a polynucleotide that hybridizes to the oligonucleotide under moderately stringent conditions, wherein the biological sample is selected from the group consisting of body fluids or cell extracts.

Document WO 98/45420 does not teach a method of repeating the steps of aformentioned (a) and (b) using a biological sample obtained from the patient at a subsequent point in time and comparing the amount of polynucleotide detected in the repeating step to the amount detected in step (b) and therefrom monitoring the progression of the cancer in the patient.

However, it would have been *prima facia* obvious to one of ordinary skill in the art at the time the claimed invention was made to duplicate the recited steps and make a comparison between the amount of polynucleotide detected in the patient's sample and amount of polynucleotide detected at a subsequenct time point(s). One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by teachings in the document, as well as established testing procedure to repeat an experiment to verify results and to thereby glean information from these results in order to monitor the progression of the cancer in the patient.

14. Applicant's amendments necessitated the new grounds of rejection presented in this office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expired THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris whose telephone number is (703)306-5880. The examiner can normally be reached on Monday through Friday from 6:30 am to 3:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703)308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Alana M. Harris, Ph.D.
Patent Examiner, Group 1642
February 12, 2001

Sheela J. Huff

SHEELA HUFF
PRIMARY EXAMINER